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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/812,776
Filing Date: March 29, 2004
Appellant(s): MUIR, DAVID F.

D.F. Muir
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/21/2008 appealing from the Office action mailed 1/30/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Co-pending US 10/218,315 was been assigned Appeal No. 2008-3327. Examiner was affirmed by BPAI Decision that was mailed to Applicant on 6/17/2008.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,448,076	DENNIS et al.	9-2002

La Fleur et al. "Basement Membrane and Repair of Injury to Peripheral Nerve: Defining a Potential Role for Macrophages, Matrix metalloproteinases, and Tissue Inhibitor of Metalloproteinases-1" Journal Of Experimental Medicine, vol 184 (December 1996), pp. 2311-2326

Lassner et al. "Preservation of Peripheral Nerve Grafts: A Comparison of Normal Saline, HTK Organ Preservation Solution, and DMEM Schwann Cell Culture Medium" Journal of Reconstructive Microsurgery, vol 11, no. 6 (November 1995), pp. 447-453

Evans et al. "The Peripheral Nerve Allograft: A Comprehensive Review of Regeneration and Neuroimmunology" Progress in Neurobiology, vol 43 (1994), pp. 187-233

Ide et al. "Schwann Cell Basal Lamina and Nerve Regeneration" Brain Research, vol 288 (1983), pp. 61-75

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

Claims 1, 6-23, 30-40, 42-56 and 117-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 38 recite a method for preparing a nerve graft with a first step of "degrading, by *in vitro* culturing, chondroitin sulfate proteoglycan of a nerve graft", thereby "enhancing post-implantation". The limitations such as "degrading CSPG" and "enhancing post-

implantation" are the intended effects of "*in vitro* culturing" as claimed. The culturing step is generic as claimed. No specific treatment agents and/or conditions are recited in the claims. Thus, it is uncertain what "degrading" and/or "enhancing" treatments are encompassed in the method for preparing a nerve graft.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-15, 17-21, 30-40, 42-51, 53-56 and 117-120, 122 and 123 are rejected under 35 U.S.C. 102(b) as being anticipated by La Fleur et al.

Claims are directed to a method for preparing a nerve tissue graft wherein method comprises 1) step of "culturing" the nerve tissue segment *in vitro* and 2) step of "killing" the nerve tissue. Some claims are further drawn to "culturing" conditions including time 24-96 hours, temperature 10 °C to 37 °C and DMEM medium. Some claims are further drawn to the nerve tissues being mammalian or rodent tissues. Some claims are further drawn to killing by chemical treatment. Some claims are further drawn to adding a generic adhesive to the nerve tissue.

The reference by La Fleur et al. discloses a method for treating mammalian nerve tissue wherein method comprises 1) step of "culturing" the nerve tissue in vitro in DMEM medium comprising various supplements at temperature 37 °C for various periods of time including 12

and 24 hours and 2) step of "killing" the nerve tissue by chemical treatment for further extraction of proteins, RNA and other components (page 2312, column 2, par. 1-2). The nerve tissues or nerve segments are held or adhered to plastic dishes and, thus, combined with a generic adhesive. The nerve tissues derived from sciatic nerves that connected to both central and peripheral nervous system tissues.

The cited reference comprises identical active steps of culturing and killing nerve tissues under conditions as presently claimed. Thus, the cited reference anticipates the claimed invention.

Claims 1, 6-15, 17-23, 30-40, 42-56 and 117-123 are rejected under 35 U.S.C. 102(b) as being anticipated by Lassner et al.

Claims are directed to a method for preparing a nerve tissue graft wherein the method comprises 1) step of culturing the nerve tissue *in vitro* and 2) step of killing the nerve tissue. Some claims are further drawn to culture conditions including time 24-96 hours, temperature 10 °C to 37 °C and DMEM medium. Some claims are further drawn to the nerve tissues being mammalian or rodent tissues. Some claims are further drawn to killing by freezing. Some claims are further drawn to adding a generic adhesive to the nerve tissue. Some claims are further drawn to additional step of performing neurite outgrowth assays in vitro and in vivo.

The reference by Lassner et al. discloses a method for preparing a nerve tissue for use as a nerve graft wherein method comprises 1) step of culturing the nerve tissue segments *in vitro* under culture conditions including temperature permissive for cellular outgrowth or 37 °C, time 48 hours and DMEM medium with serum, and 2) step of killing the nerve tissue by freezing at

minus 18 °C; for example: see page 448, column 2, last paragraph that relates to the second series of experiments. The nerve tissues or nerve segments are held or adhered to plastic dishes and, thus, combined with a generic adhesive. The nerve tissues derived from sciatic nerves that connected to both central and peripheral nervous system tissues. The cited reference also describes neurite outgrowth assays *in vitro* (figures 5 and 7) and *in vivo* regeneration upon reimplantation (page 449, col. 1).

The cited reference comprises identical active steps of culturing and killing nerve tissues under conditions as presently claimed. Thus, the cited reference anticipates the claimed invention.

Claims 1, 6-15, 17-21, 30-32, 34-40, 42-45, 47-51, 53-56, 119, 122 and 123 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,448,076 (Dennis et al).

Claims are directed to a method for preparing a nerve tissue graft wherein the method comprises 1) step of culturing the nerve tissue *in vitro* and 2) step of killing the nerve tissue. Some claims are further drawn to culturing conditions including time 24-96 hours, temperature 10 °C to 37 °C and a medium. Some claims are further drawn to the nerve tissues being mammalian or rodent tissues. Some claims are further drawn to killing by chemical treatment. Some claims are further drawn to adding a generic adhesive to the nerve tissue. Some claims are further drawn to additional step of performing neurite outgrowth assays in vitro and in vivo.

US 6,448,076 discloses a method for preparing a nerve tissue for use as a nerve graft (entire document including abstract) wherein the method comprises step of culturing *in vitro* the nerve graft in a medium or in a balanced salt solution (col. 3, lines 45-46), step of rendering the

nerve graft acellular by chemical treatment (col. 3, lines 47-67 and col. 4, lines 26). The nerve graft is a mammalian peripheral nerve segment (col. 3, line 42). The cited patent encompasses the use of room temperature in the method for making a nerve graft. Thus, the cited patent US 6,448,076 appears to teach the same active steps and the same structural elements in the method of making graft as claimed. The acellular nerve grafts were used to repair nerve gap in vivo (col. 4, lines 47-60) and results were evaluated in vitro (col. 5, lines 53-66). The cited patent US 6,448,076 teaches that the nerve graft made supported axonal regeneration and allowed for end-organ reinnervation (col. 6, line 21-24) and, thus, enhanced post-implantation traversal of an interface between the nerve graft and host tissue within the meaning of the claims.

Therefore, US 6,448,076 anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-23, 30-40, 42-56 and 117-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,448,076 (Dennis et al), La Fleur et al., Ide et al. and Evans et al..

Claims are directed to a method for preparing a nerve tissue graft wherein the method comprises 1) step of culturing the nerve tissue *in vitro* and 2) step of killing the nerve tissue. Some claims are further drawn to culture conditions including time 24-96 hours, temperature 10 °C to 37 °C and a medium. Some claims are further drawn to the nerve tissues being

mammalian including rodent and human. Some claims are further drawn to step of killing by freezing or by chemical treatment. Some claims are further drawn to adding a generic adhesive to the nerve tissue. Some claims are further drawn to additional step of performing neurite outgrowth assays in vitro and in vivo.

US 6,448,076 (Dennis et al) is relied upon for disclosure of a method for preparing a nerve tissue graft as intended for implantation (entire document including abstract) wherein the method encompasses 1) step of *in vitro* culturing and 2) step of rendering the nerve graft acellular by killing the cells.

In particular, the cited patent US 6,448,076 (Dennis et al) discloses a chemical treatment for making acellular nerve grafts and lacks explicit teaching about rendering nerve graft acellular through killing by freezing. However, Evans et al. teaches freezing and thawing of nerve grafts for making the nerve grafts acellular and non-immunogenic (page 212. col. 2, last par.). The cited reference by Ide et al teaches that basal lamina of Schwann cells rather than living cells play important role in nerve regeneration after implantation of nerve graft (page 62, col. 1, par. 1).

The cited patent US 6,448,076 (Dennis et al) teaches the use of PBS or physiological balanced salt solution for "culturing" or for pre-treatment before acellularization step. But it lacks an explicit teaching about the use of an enriched cell culture media. However, La Fleur reference teaches that incubation of nerve segments in complete cell culture medium with various supplements results in upregulation of TIMP-1 expression and that TIMP-1 protects basement membrane of nerve tissue from uncontrolled disintegration or degradation after injury in the *in vivo* system (abstract). La Fleur reference teaches incubation of nerve segments in cell

culture media at temperature 37 °C for periods of time including 12 and 24 hours (page 1212, col. 2, par. 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute a supplemented culture medium for a buffered salt solution in two-step method of US 6,448,076 (Dennis et al) with a reasonable expectation in success in making nerve tissues as intended for nerve grafts because culturing nerve tissues promotes up-regulation of compounds that remodel basement membrane of nerve tissues and protect from uncontrolled degradation after injury as adequately taught by La Fleur et al.

One of skill in the art would have been motivated to kill the nerve graft living tissues in order to avoid tissue rejection upon transplantation as clearly taught by Evans et al., killing by chemical treatment and killing by freezing are considered to be substitution of equivalents.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

(10) Response to Argument

Response to Arguments

Applicant's arguments filed 5/21/2008 have been fully considered but they are not found persuasive.

I. With regard to the claim rejection under 35 U.S.C. 112, second paragraph, (indefinite), applicant argues that claimed invention is misread and that the first step is not a culturing step

but it is rather a step of degrading chondroitin sulfate proteoglycan (CSPG) that is achieved by means of culturing (appeal brief page 7). However, independent claim 1 does not recite any culturing "means" as argued. Independent claim 38 recites only time and temperature intervals that still do not clearly point out any means or any specific limitations (enzymes, for example) that provide for degradation of CSPG. The claimed time ranges (24-96 hours) and temperature ranges (10-37 °C) are those that that are commonly used for culturing and for maintenance of viable cells and tissues and, thus, by themselves the claimed time and temperature conditions cannot be reasonably considered as providing for degradation of cells or cellular matrices.

Applicant further argues that instant specification provides for ample teaching regarding culturing conditions required to degrade CSPG and that these conditions would be "predegenerating" conditions that allow "the living nerve cells to express CSPG-degrading enzymes and promote Schwann cell proliferation, as would occur naturally *in vivo* during the remodeling process of nerve degeneration" (specification, page 27, lines 10-23.) However, these definitions are rather broad. It appears as argued and as disclosed that "predegeneration conditions" are those that provide for remodeling of nerve tissue and that the remodeling of nerve tissues is obtained under "predegeneration conditions". Thus, both applicant's arguments and definitions are circular and they do not clearly point out any specific parameters for the culture conditions during culturing step and/or they do not clearly point out any specific elements as encompassed in the step of "degrading by *in vitro* culturing". Considering the broadest definitions for culturing under "predegeneration" conditions, it would be reasonably to assume that the viable cells that are cultured *in vitro* would inherently provide for the same effects

(protein or enzyme expression and cell proliferation, for example) as viable cells *in vivo* to at least some extend just by the virtue being/remaining living or viable.

II. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by La Fleur et al. Applicant argues that the cited reference neither discloses nor suggest the claimed method because it relates to effects that are essentially opposite of the claimed invention since the claimed method recites a degradation of GSPG by "culturing" a nerve segment but La Fleur teaches that TIMP-1 (inhibitor of MMP) protects basement membrane from exogenous MMP during degeneration (appeal brief pages 8-9). At the very least this argument is not found persuasive because the cited reference discloses method for making a nerve tissue segment that comprises identical active steps such as 1) step of generic "culturing" a nerve tissue segment *in vitro* and 2) step of killing the nerve tissue (page 2312, column 2, par. 1-2). The claimed culture conditions are either generic (claim 1) or the claimed culture conditions including temperature, time and basic medium (claim 38, for example) are the same as recited for a culturing step in the cited reference. Thus, the intended final effects including "degrading CSPG" and "enhancing post-implantation" for remodeling/modifying nerve tissue segments cultured *in vitro* would be the same due to the use of identical "culturing" conditions. Moreover, the cited reference teaches that TIMP (inhibitor of MMP) helps to preserve Schwann cell basal lamina (BM) during degeneration, thus promoting axonal regrowth *in vivo* upon implantation (page 2323, col. 2, last 2 lines) and that the TIMP expression was upregulated when nerve explants were incubated or cultured *in vitro* (abstract). Although the reference teaches that TIMP regulate proteolysis *in vivo*, the reference does not teach that TIMP would suppress expression of other proteins

including CSPG degrading enzymes. Even more, the reference teaches that there is evidence for expression of both proteinases and their inhibitors in the *in vitro* system or during *in vitro* culturing (page 2312, col.1, par. 2, lines 1-3).

Applicant further argues that the cited method would not inherently provide for the same effects as claimed (appeal brief pages 9-12). First, applicant argues that the cited method is not identical to the claimed method because one of the disclosed protocols includes crushing nerve segments (page 10, last paragraph). Upon review it is not found particularly true because crushing of nerve segments was used only for making conditioned medium. The other protocol that is described on page 2312, col. 2, par. 2 is relied upon in the office action for the teaching of active steps of culturing nerve segments and killing cells in the nerve segment by chemical treatment.

Second, Applicant argues (page 11, par. 1) that the cited reference does not teach that the nerve segment would have "intact basal lamina tube structure" as required by the claims because the reference discloses homogenization of the nerve segment at the last paragraph of column 2 at page 2312. Upon review it is not found particularly true because homogenization that is argued was used for a gelatinase assay. The other protocol that is described on page 2312, col. 2, par. 2 is relied upon in the office action for the teaching of active steps of culturing nerve segments and killing cells in the nerve segment by chemical treatment. Moreover, the reference clearly identifies the nerve segments, which were cultured and then chemically treated with Trisol reagent for RNA extraction and for evaluation of cytokine and TIMP expression, as "undamaged" nerve explants (see abstract/summary at line 14).

Third, Applicant argues (page 11. par. 2 and page 12, par. 1) that the cited method as disclosed by La Fleur et al. is not a method for making a nerve graft suitable for implantation because the disclosed final step involves the use of Trizol solution containing phenol that is toxic and could cause necrosis, coma and death. Yet, the final step of the claimed method involves "killing" cells in the nerve tissue graft (claims 1 and 38) including "killing" cells by some generic "chemical treatment" (claims 21 and 49, for example). Further, the Trizol reagent is known to disrupt cells while maintaining integrity of cellular components. Furthermore, it is quite reasonable to assume that one of skill in the art would rinse the tissue grafts before graft implantation in order to remove any toxic chemical reagents including chemical reagents used for preparing grafts and/or for "killing" cells in the graft. Applicants do not have a step of subsequently removing the killing reagents in the claims, and therefore clearly rely on the person of ordinary skill in the art to know that the killing reagent should be rinsed away before implantation.

III. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by Lassner et al. Applicant argues (appeal brief page 12-14) that the cited reference describes several experimental groups including cold, ischemic conditions that are not physiological conditions promoting degradation of CSPG. Yet, the rejected claims do not recite any specific conditions that lead to the intended effects such as promoting degradation of CSPG. The cited reference clearly discloses second series of experiments that involve steps of "culturing" nerve segments in DMEM on the bench or at room temperature for 2 days and subsequent killing by freezing (page 148, col. 2, last paragraph) as explained above. Moreover, the cited reference

teaches that the cells of nerve segments of the second series of experiments proliferated as demonstrated by cellular outgrowth (see fourth line from the bottom of col. 2, on page 448). Thus, the disclosed conditions meet the applicant's definitions for "predegenerating" conditions as presently argued (paragraph bridging appeal brief pages 7 and 8) since the culturing conditions of the cited reference provided for cell proliferation during "culturing" step.

Further, the experimental groups of table 1, which are argued, are the pre-treatment protocols of nerve segments of the second series of disclosed experiments. Moreover, not all experimental groups were subjected to the pre-treatment with cold ischemia. Furthermore, the claimed method is open to any pretreatment before first step recited in the instant claim 1 and 38 by the virtue of open language "comprising".

Applicants appear to argue that the second series of experiments disclosed by Lassner are intended for histological evaluation and involve the use of a toxic compound such as methanol. Yet, the final step of the claimed method involves "killing" cells (claims 1 and 38) including "killing" by generic "chemical treatment" (claims 21 and 49, for example). Thus, the active steps are identical as required by the claimed method and the culture conditions are the same within the broadest reasonable meaning of the claims. Furthermore, it is quite reasonable to assume that one of skill in the art would rinse the tissue grafts before graft implantation in order to remove any toxic chemical reagents including chemical reagents used for preparing grafts and/or for "killing" cells in the graft. Applicants do not have a step of subsequently removing the killing reagents in the claims, and therefore clearly rely on the person of ordinary skill in the art to know that the killing reagent should be rinsed away before implantation.

With respect to the argument that the cited reference teaches making a nerve tissue histological sample but not a nerve graft suitable for implantation, it is noted that the nerve graft suitable for implantation is a nerve segment and thus, it does not appear to be different from a nerve tissue histological sample that is also a nerve segment.

IV. With regard to the claim rejection under 35 U.S.C. 102(b) as being anticipated by US 6,448,076 (Dennis et al) Applicant argues (appeal brief pages 15-18) that Dennis does not recite the presently claimed effects including "degrading CSPG" and "enhancing post-implantation" and it rather relates to preservation of basal lamina. Yet, the final effects with regard to remodeling nerve tissue segment *in vitro* are considered to be the same as result of the same active step of "*in vitro* culturing". The claimed "*in vitro* culturing" conditions are generic (claim 1) or the claimed "*in vitro* culturing" encompasses temperature and time (claim 38, for example) that are common parameters for cell maintenance or cell culturing on a laboratory bench and, by themselves, the claimed time and temperature conditions cannot be reasonably considered as providing for degradation of cells or cellular matrices.

Applicant also argues that the method as disclosed by US 6,448,076 (Dennis et al) involve toxic chemicals including glycerol and Triton X-100 that cause damage to structural integrity of tissue and basal lamina (appeal brief page 17). Yet, the final step of the claimed method involves "killing" cells in the nerve tissue graft (claims 1 and 38) including "killing" cells by a generic "chemical treatment" (claims 21 and 49, for example).

Applicant also argues that the nerve grafts treated with Triton X-100 as taught by the cited US 6,448,076 (Dennis et al) would not have "intact basal lamina tube structure" in the light

by IDS references by Hudson et al. and Sondell et al. This argument does not appear to have any persuasive grounds for the very least reason that limitation "intact basal lamina tube structure" is encompassed in the first step of "degrading by *in vitro* culturing" of an intermediate product in the presently claimed method.

In response to applicant's argument it is also noted that a recitation of the intended use or effects of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the final nerve grafts made by the cited method as disclosed by US 6,448,076 (Dennis et al) were implanted and provided for axonal regeneration after implantation (col. 6, line 24). Thus, the cited method for making nerve graft that comprises same steps of "degrading by *in vitro* culturing" (maintenance in PBS or physiological saline) and "killing" by "chemical treatment" (treatment with solutions of chemical reagents) modifies the starting nerve graft material to the same the degree as encompassed by the claimed invention as to provide for sufficient integrity of basal lamina tubes in order to support axonal regeneration after implantation within the meaning of the instant claims.

V. With regard to the claim rejection under 35 U.S.C. 103 applicants appear argue (appeal brief pages 19-21) that there is no suggestion to combine cited references. However, the cited references are in the same field of endeavor such as method of making nerve grafts intended for repairing nerve damage in vivo and they seek to solve the same problems as the instant application and claims such as provide for nerve grafts intended for nerve damage repair

in vivo, and one of skill in the art is free to select components available in the prior art, *In re* Winslow, 151 USPQ 48 (CCPA, 1966).

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided in the image file wrapper.

See the co-pending US 10/218,315 which was assigned Appeal No. 2008-3327. Examiner was affirmed by BPAI Decision that was mailed to Applicant on 6/17/2008.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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